JUL 25 2003

K031981

510(k) Summary
Linvatec Biomaterials
2.4 SmartNail

Submitter's Name, Address, Telephone Number, and Contact Person

Linvatec Biomaterials Ltd.
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Director, Quality and Regulatory Affairs
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Finland, Europe
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Date prepared: June 19, 2003

Name of the device:

A.	Trade or Proprietary Name:	2.4 SmartNail
B.	Common Name:	Absorbable Bone Fixation Nail
C.	Classification Name:	Bone Fixation Nail
D.	Device Product Code:	MAI and HWC

Predicate Device:

1. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) SmartNail (K993074)
2. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) 1.5mm Bone Fixation Kit (K012000, K013546)

Intended Use:

Properly used, in the presence of adequate immobilization, 2.4 SmartNail is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

2.4 SmartNail is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g.,patient conditions, including blood supply limitations, insufficient quantity or quality of bone; active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4)

Treatment of physeal fractures in children, because the effect of the implant upon the healing of growth plate has not been tested clinically.

Device Description:

The device description of the 2.4mm SmartNail implant is as follows.

- The implant is composed of poly-96L/4D-lactide copolymer. This is the very same implant raw material with SmartNail (K993074) and 1.5mm Bone Fixation Kit (K012000, K013546)
- Lengths of implant are 16, 25, 35 and 45 mm. The current product selection of SmartNail products contains 16, 20 and 25 mm long implants. The current product selection of 1.5mm Bone Fixation Kit contains 14, 16, 18, 20 and 25mm long implants
- Diameter of implant is 2.4 mm.
- Shelf life is same with SmartNail™ and 1.5mm Bone Fixation Kit (K012000, K013546), 3 years.
- Our current packaging style of SmartNail is that aluminium pouch is inner and tyvek®-pouch is outer pouch, implant is placed into cardboard holder. This packaging method is identical for 1.5mm and 2.4 SmartNail implants.

The only modifications that were made are:

- Amendment of one new sizes, 2.4mm in diameter and lengths of 16, 25, 35 and 45 mm
- Revision of design accordingly in longer lengths, more rows of barbs than in shorter nails
- Reference numbers for new sizes. These changes are updated in labelling.
- Revision of instrumentation accordingly
- Amendment of optional silicone cover for improvement of arthroscopic surgical technique

Substantial Equivalence:

Linvatec Biomaterials Ltd (the previous Bionx Implants Inc.) 2.4 SmartNail is substantially equivalent to the cleared Linvatec Biomaterials Ltd (the previous Bionx Implants Inc.) SmartNail (K993074) and 1.5mm Bone Fixation Kit (K012000, K013546). These changes in design do not raise any new concerns of safety and efficacy of the implant. This modification has no effect on pull-out properties of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Linvatec Biomaterials Ltd.
P.O. Box 3
FIN-33721 Tampere
Finland

Re: K031981
Trade Name: 2.4 SmartNail
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, HWC
Dated: June 19, 2003
Received: June 26, 2003

Dear Ms. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K031981

Device Name: **2.4 SmartNail**

Indications for Use:

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(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031981